

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA**

UNITED STATES of AMERICA, ex rel.)
JUAN N. WALTERSPIEL, M.D.,)
F.A.A.P.)

Plaintiff/Relator,)

v.)

Cause No. 1:09-CV-01086-JMS-DML

BAYER A.G., QUINTILES)
TRANSNATIONAL CORP., JOHN)
DOE, JOE DOE AND JANE DOE)

Applicant.)

**QUINTILES TRANSNATIONAL CORPORATION
MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS
PURSUANT TO FED. R. CIV. P. 12(b)(6) and 9(b)**

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TABLE OF CONTENTS

Page

I.	Procedural Background and Parties	1
II.	Summary of Applicable Regulatory Provisions and Material Allegations.....	2
A.	FDA Regulatory Provisions Related to Market Exclusivity.....	3
B.	Complaint Allegations	6
C.	Summary of Quintiles' Legal Arguments for Dismissal	7
D.	False Claims Act Retroactivity Issues	9
III.	Legal Argument	12
A.	The Allegations Present No Actionable Conduct Under the False Claims Act As A Matter of Law	12
1.	Actionable False Claims Are Not Alleged.....	12
2.	Actionable False Statements or False Records Are Not Alleged	14
3.	Actionable Conspiracy Is Not Alleged	18
B.	The Complaint Allegations Do Not Meet the Heighted Pleading Standards of Fed. R. Civ. P. 9(b) Compelling Dismissal of this Action	19
	Conclusion	20

TABLE OF AUTHORITIES

CASES	Page(s)
<i>Abner v. Jewish Hosp. Health Care Servs.</i> , No. 4:05-cv-0106-DFH-WGH, 2008 WL 3853361 (S.D. Ind. Aug. 13, 2008).....	19, 20
<i>Allison Engine Co. v. United States ex rel. Sanders</i> , 553 U.S. 662 (2008).....	13
<i>Ashcroft v. Iqbal</i> , 129 S.Ct. 1937 (2009).....	8
<i>Graham County Soil & Water Conservation Dist. v. U.S. ex rel. Wilson</i> , 130 S. Ct. 1396 (2010).....	10
<i>Gross v. AIDS Research Alliance-Chicago</i> , No. 01 C 8182, 2004 WL 905952 (N.D. Ill. Apr. 27, 2004).....	18
<i>Harrison v. Westinghouse Savannah River Co.</i> , 176 F.3d 776 (4th Cir. 1999)	14, 16, 17
<i>Hefferman v. Bass</i> , 467 F.3d 596 (7th Cir. 2006)	19
<i>Hopper v. Solvay Pharma., Inc.</i> , 588 F.3d 1318 (11th Cir. 2009)	8, 11
<i>In U.S. ex rel. Main v. Oakland City Univ.</i> , 426 F.3d 914 (7th Cir. 2005)	15, 16
<i>Indiana Funeral Dirs. Ins. Trust v. Trustmark Ins. Corp.</i> , 347 F.3d 652 (7th Cir. 2009)	21
<i>Lusby v. Rolls-Royce Corp.</i> , 570 F.3d 849 (7th Cir. 2009)	8, 20
<i>Rodriguez v. United States</i> , 286 F.3d 972 (7th Cir. 2002)	21
<i>Scherer v. Balkema</i> , 40 F.2d 437 (7th Cir. 1988)	18
<i>U.S. ex rel. Carter v. Halliburton Co.</i> , No. 1:08-cv-1162, 2009 WL 2240331 (E.D. Va. 2009)	11

<i>U.S. ex rel. Gross v. Aids Research Alliance-Chicago</i> , 415 F.3d 601 (7th Cir. 2005)	7, 15, 18
<i>U.S. ex rel. Grubbs v. Kanneganti</i> , 565 F.3d 180 (5th Cir. 2009)	8
<i>U.S. ex rel. Kennedy v. Aventis Pharma., Inc.</i> , No. 03-C-2750, 2008 WL 5211021 (N.D. Ill. Dec. 10, 2008).....	7
<i>U.S. ex rel. Mikes v. Straus</i> , 274 F.3d 687 (2d Cir. 2001).....	7
<i>U.S. ex rel. Polansky v. Pfizer, Inc.</i> , 2009 WL 1456582 (E.D.N.Y. May 22, 2009)	8
<i>U.S. ex rel. Radcliffe v. Purdue Pharma L.P.</i> , 582 F. Supp. 2d 766 (W.D. Va. 2008)	8
<i>U.S. ex rel. Rost v. Pfizer, Inc.</i> , 507 F.3d 720 (1st Cir. 2007).....	8
<i>U.S. ex rel. Sanders v. Allison Engine Co., Inc.</i> , 667 F. Supp. 2d 747 (S.D. Ohio 2009) (retroactivity provision only applies to “claims” pending—not cases—as of June 7, 2008 and noted that a claim is defined as a “request or demand . . . for money or property” under the FCA)	11
<i>U.S. ex rel. Stephens v. Tissue Sci. Labs.</i> , 664 F. Supp. 2d 1310 (N.D. Ga. 2009)	7
<i>U.S. ex rel. Thompson v. Columbia/HCA Healthcare</i> , 125 F.3d 899 (5th Cir. 1997)	7
<i>U.S. ex rel. West v. Ortho-McNeil Pharma., Inc.</i> , No. 03-C-8239, 2007 WL 2091185 (N.D. Ill. July 20, 2007)	8
<i>U.S. v. Aquillon</i> , 628 F. Supp. 2d 542 (D. Del. 2009).....	11
<i>U.S. v. Sci. Applications Int’l Corp.</i> , 653 F. Supp. 2d 87 (D.D.C. 2009).....	11
<i>United States ex rel., Hagood v. Sonoma County Water Agency</i> , 929 F.2d 1416 (9th Cir. 1991)	16
<i>United States ex rel. Coots v. Reid Hosp. & Health Care Servs., Inc.</i> , No. 1:10-cv-0526-JMS-TAB, 2012 WL 1098930 (S.D. Ind. April 2, 2012)	19

<i>United States ex rel. Crews v. NCS Healthcare of Illinois, Inc.</i> , 460 F.3d 853 (7th Cir. 2006)	15, 18
<i>United States ex rel. Durcholz v. FKW Inc.</i> , 189 F.3d 542 (7th Cir. 1999)	18
<i>United States ex rel. Fowler v. Caremark RX, L.L.C.</i> , 496 F.3d 730 (7th Cir. 2007), <i>overruled on other grounds by Glaser v. Wound Care Consultants, Inc.</i> , 570 F.3d 907 (7th Cir. 2009)	13, 15
<i>United States ex rel. Garst v. Lockheed-Martin Corp.</i> , 328 F.3d 374 (7th Cir. 2003)	19
<i>United States ex rel. Hudalla v. Walsh Constr. Co.</i> , No. 05 C 5930, 2011 WL 6028315 (N.D. Ill. Dec. 3, 2011)	10, 11, 13
<i>United States ex rel. Schwedt v. Planning Research Corp.</i> , 59 F.3d 196 (D.C. Cir. 1995)	16
<i>United States ex rel. Wildhirt v. AARS Forever, Inc.</i> , No. 09-C-1215, 2011 WL 5373985 (N.D. Ill. Nov. 4, 2011)	14, 17
<i>United States ex rel. Yannacopoulos v. Gen. Dynamics</i> , 652 F.3d 818 (7th Cir. 2011)	10
<i>United States v. Hawley</i> , No. 06 C 4087, 2011 WL 3295419 (N.D. Iowa Aug. 1, 2011)	11
<i>United States v. Northshore Univ. HealthSystem</i> , 660 F. Supp. 2d 891 (N.D. Ill. 2009)	10, 11
<i>United States v. Omnicare, Inc.</i> , No. 07-C-5777, 2011 WL 1059148 (N.D. Ill. March 21, 2011)	15, 18

STATUTES

21 U.S.C. § 355a(b)(1)	4
21 U.S.C. §§ 355a(b)(1), (c)(2)	4
21 U.S.C. § 355a(d)(3)	4, 5
21 U.S.C. § 3729(b)(2) <i>et seq.</i>	14
31 U.S.C. § 3729(a)(1)	12, 13, 14
31 U.S.C. § 3729(a)(1)(A)	10

31 U.S.C. § 3729(a)(1)(B)	10
31 U.S.C. § 3729(a)(1)(C)	10, 18
31 U.S.C. § 3729(a)(1).....	10
31 U.S.C. § 3729(a)(2).....	10
31 U.S.C. § 3729(a)(3).....	10
31 U.S.C. § 3729(b)	13
31 U.S.C. § 3729(b)(4)	15
31 U.S.C. § 3730(a)(2).....	1
31 U.S.C. § 3730(a)(3).....	1
31 U.S.C. § 3730(d)(1)-(2)	1
False Claims Act, 31 U.S.C. § 3730(b).....	1
Food and Drug Administration Modernization Act of 1997 (“FDAMA”) Pub. L. 105-111, 111 Stat. 2305 (codified at 21 U.S.C. § 355a)	4, 5
Fraud Enforcement and Recovery Act of 2009, Pub. L No. 111-21, 123 Stat. 1617, 1621 (2009).....	9
Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 185 (2010).....	9

OTHER AUTHORITIES

Fed. R. Civ. P. 9(b)	1, 8, 19, 20
Fed. R. Civ. P. 10(a)	8
Fed. R. Civ. P. 12(b)(6)	1, 11
FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION AND RESEARCH, <i>Division Director Review – Ciprofloxacin for Complicated Urinary Tract Infections and Pyelonephritis in Pediatric Patients,</i> http://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/019537s049_019847s027_ 019857s031_020780s013_ODMemo.pdf	2, 3

FOOD & DRUG ADMIN., DIVISION OF SPECIAL PATHOGEN AND IMMUNOLOGIC DRUG PRODUCTS, <i>Approval Letter from Renata Albrecht, M.D., Director. to Andrew Verderame, Director, Regulatory Affairs, Bayer Pharmaceuticals Corp.</i> (Mar. 25, 2004), http://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/019537s049_019847s027_019857s031_020780s013_Approv.pdf	2
FOOD & DRUG ADMIN., <i>Division Directors' Memorandum, Supplemental Applications for Inhalation Anthrax (Post-exposure)</i> (August 29, 2000), http://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/19-537S038_Cipro_admindocs.pdf	3
U.S. DEP'T OF HEALTH AND HUMAN SERVS., FOOD AND DRUG ADMIN., CTR. FOR DRUG EVALUATION AND RESEARCH, <i>APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS 127</i> (32d ed. 2012) http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf f.	3

Defendant Quintiles Transnational Corporation (“Quintiles”), by its undersigned counsel, submits the following Memorandum of Law in support of its Motion to Dismiss this action with prejudice pursuant to Federal Rule of Civil Procedure 12(b)(6) and 9(b) for failure to state an actionable claim; and, for failure to plead fraud with sufficient legal particularity as to Quintiles.

I. Procedural Background and Parties.

Juan N. Walterspiel, M.D. (“Relator”), filed this action under seal on September 1, 2009, pursuant to the private citizen provisions of the civil False Claims Act, 31 U.S.C. § 3730(b), which provides limited jurisdiction for private citizens known as “relators” to pursue allegations of fraud on behalf of the United States that relate to and impact the federal treasury. In the event of a settlement or judgment related to the allegations, the relator is entitled to a percentage of the amount recovered for the United States. 31 U.S.C. § 3730(d)(1)-(2).

The named defendant parties in this action are Bayer A.G. (“Bayer”), Quintiles, Joe Doe (unknown Bayer employee or contractor), John Doe (unknown Quintiles employee or contractor), and Jane Doe (unknown Quintiles employee or contractor). The “Doe” defendant parties have not been identified in the suit, apparently waiting for “discovery” and the opportunity for amendment with leave of Court. Compl. ¶¶ 25-30. By statute, the U.S. Department of Justice (“DOJ”) is required to undertake a diligent evaluation of the allegations for sixty days (60) to determine if it will “take over” the suit or, alternatively, decline to intervene and allow the relator to proceed with the allegations on behalf of the United States, the real party in interest. 31 U.S.C. § 3730(a)(2). Extensions of the 60-day period may be sought for good cause. 31 U.S.C. § 3730(a)(3).

It is common practice for DOJ to seek these extensions *ex parte* with no notice to the parties that are named defendants in the action. In this case, Quintiles was unaware that it was

named as a defendant in a False Claims Act action filed in September, 2009 until it was served the Complaint in March, 2012 by the relator, though DOJ had sought records from Quintiles during DOJ's evaluation period. Docket at 36. DOJ has discretion to partially lift the seal and notify parties of their status in a False Claims Act *qui tam* action at any time during its evaluation period.

DOJ evaluated this matter for approximately 30 months and eventually entered a notice of declination on December 6, 2011. Docket at 29. This Court subsequently entered a December 7, 2011 order to unseal the complaint and serve the summons and the complaint on the Defendants. Docket at 30. On or about March 30, 2012, service of the summons and complaint was received by Quintiles. By agreement of the parties, with leave of the Court, the agreed date for any responsive pleading by Quintiles to the served Complaint was established as June 20, 2012. Docket at 46. To date, Bayer has not been served in this action and there is a pending show cause to dismiss Bayer for non-service pursuant to the Court's December 7, 2011 unsealing order. Docket at 44.

II. Summary of Applicable Regulatory Provisions and Material Allegations.

Much of the complaint presents as a redundant ramble of alleged bad acts by Bayer in other irrelevant clinical study matters.¹ Distilled to the bare essentials of the few allegations

¹ The complaint does not identify the Cipro products at issue. The public record reveals that the pediatric studies cited by Relator covered numerous ciprofloxacin products with varying lengths of marketing exclusivity. FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION AND RESEARCH, CTR, *Division Director Review – Ciprofloxacin for Complicated Urinary Tract Infections and Pyelonephritis in Pediatric Patients*, http://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/019537s049_019847s027_019857s031_020780s013_ODMemo.pdf. There are other allegations that are not clearly germane or are contradicted by the public record. For example, Relator asserts that pediatric study data were falsified, “which hid adverse effects of Ciprofloxacin in children” Compl. ¶ 60. However, the public record reveals that, based on its review of the pediatric study data at issue, FDA approved a labeling change that directly addresses the adverse effects of ciprofloxacin in children: “Although effective in clinical trials, ciprofloxacin is not a drug of first choice in the pediatric population due to an increased incidence of adverse events compared to controls, including events related to joints and/or surrounding tissues.” FOOD & DRUG ADMIN., DIVISION OF SPECIAL PATHOGEN AND IMMUNOLOGIC DRUG PRODUCTS, *Approval Letter from Renata Albrecht, M.D., Director. to Andrew Verderame, Director, Regulatory Affairs, Bayer*

actually related to Quintiles, this Court may consider both what has been alleged in the complaint and, importantly, what is not in the complaint that is legally necessary to sustain a False Claims Act action against Quintiles.

A. FDA Regulatory Provisions Related to Market Exclusivity.

Quintiles is a biopharmaceutical services company that provides clinical trial management services to assist the development and completion of clinical research and clinical trials for a wide variety of pharmaceutical, biologic and medical devices companies, including Bayer. It is alleged that Quintiles assisted Bayer with the collection of research data in connection with a Food and Drug Administration (“FDA”) approved clinical study of the drug Cipro, an antibiotic, focused on pediatric use. Compl. ¶ 24. The clinical study was voluntarily undertaken at the request of the FDA to better understand pediatric use of Cipro.² At the time of the study, Cipro was an approved drug sold in the United States.³ Bayer holds the approvals of Cipro.⁴

Pharmaceuticals Corp. (Mar. 25, 2004), http://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/019537s049_019847s027_019857s031_020780s013_Approv.pdf. Another odd allegation contradicted by the public record relates to the inhalation anthrax indication. The public record indicates that FDA was aware of the potential adverse effects of ciprofloxacin in the pediatric population, including effects related to joints. *See* FOOD & DRUG ADMIN., *Division Directors’ Memorandum, Supplemental Applications for Inhalation Anthrax (Post-exposure)* (August 29, 2000), http://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/19-537S038_Cipro_admindocs.pdf (“Fluoroquinolones, including ciprofloxacin, are currently not indicated for treatment of any pediatric infections because these agents, as a class, have been shown to cause arthropathy in weight-bearing joints of juvenile animals, particularly dogs.”). However, given the high mortality rate of inhalation anthrax (80%-100%), FDA’s risk-benefit assessment favored use of ciprofloxacin in a post-exposure situation. *Id.* Relator’s suggestion that further data confirming these pediatric joint-related adverse effects would alter FDA’s risk-benefit analysis for the treatment of a disease with an 80%-100% mortality rate defies logic. None of these allegations, however, have any legal bearing to potential False Claims Act liability or involve Quintiles directly or indirectly.

² FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION AND RESEARCH, CTR, *Division Director Review – Ciprofloxacin for Complicated Urinary Tract Infections and Pyelonephritis in Pediatric Patients*, at 3 http://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/019537s049_019847s027_019857s031_020780s013_ODMemo.pdf.

³ *Id.*

⁴ U.S. DEP’T OF HEALTH AND HUMAN SERVS., FOOD AND DRUG ADMIN., CTR. FOR DRUG EVALUATION AND RESEARCH, *APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS* 127 (32d ed. 2012) <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf>.

In 1997, Congress passed the Food and Drug Administration Modernization Act of 1997 (“FDAMA”), which included a provision that would extend a drug company’s market exclusivity for a particular drug for a period of six (6) months if the company conducted pediatric studies that had been specifically requested by the FDA. Pub. L. 105-115, 111 Stat. 2305 (codified at 21 U.S.C. § 355a). In exchange for completing the FDA clinical study and submitting the study results to the FDA, Bayer was authorized to claim a six (6) month extension of its “exclusivity” in the marketplace for Cipro, meaning that the FDA would forestall for an additional six months the approval of any new drug application for a generic version of Cipro by a competitor or a generics company. 21 U.S.C. § 355a (b)(1). The effect of such exclusivity does not impact any approved drugs already in the marketplace or that do not have substantially equivalent ingredients to Cipro. *See id.* Further, the right to exclusivity is not based on the results of the clinical study, *i.e.*, positive or negative data generated to support the use of the drug in a particular pediatric population. 21 U.S.C. § 355a(d)(3).

Section 355a sets out the process for obtaining market exclusivity extensions through pediatric drug studies. To qualify for pediatric exclusivity, the FDA must issue a Written Request to the company seeking or holding FDA approval for a particular drug product (also known as the “sponsor”) for the submission of certain studies to determine if the drug could provide meaningful health benefits in the pediatric population. 21 U.S.C. §§ 355a(b)(1), (c)(2). The sponsor is not required to perform pediatric studies in response to a Written Request; however, if the sponsor chooses to perform the studies to obtain pediatric exclusivity, the sponsor must submit reports of the study results to the FDA in accordance with the timeframe set forth in the Written Request. 21 U.S.C. §§ 355a(b)(1), (c)(2). The FDA must then review the submitted reports and determine, within 180 days after the submission of the reports, whether to

accept or reject such reports. 21 U.S.C. § 355a(d)(3). It is this decision alone that determines whether the sponsor of the study will be granted the six-month market exclusivity extension for the tested drug.

Section 355a(d)(3) further provides “[t]he Secretary’s only responsibility in accepting or rejecting the reports shall be to determine, within the 180-day period, whether the studies fairly respond to the written request, have been conducted in accordance with commonly accepted scientific principles and protocols, and have been reported in accordance with the requirements of the Secretary for filing.” 21 U.S.C. § 355a(d)(3). Noticeably absent from the acceptance criteria is a requirement that the study reports include positive results for the use of the drug in the pediatric population. *Id.* There are no other requisite conditions for the grant of the 6-month pediatric exclusivity extension. *Id.*

Consequently, a grant of market exclusivity extension under Section 355a is not dependent on the outcome of the study. Rather, it is dependent on the sponsor completing the study and reporting the study results in accordance with the terms of FDA’s Written Request and “commonly accepted scientific principles and protocols.” *Id.* Accordingly, though wrong and subject to remedy by administrative, civil and criminal statutes other than the civil False Claims Act, falsifying data to achieve a more positive or efficacious result would not increase a sponsor’s chance of receiving market exclusivity. Even if the pediatric study proves that the drug is not safe or effective when used in children, the six-month market exclusivity extension would still be granted, as long as the Secretary determines the requirements for accepting the study reports were met. The Relator’s “story” of Bayer’s motives and actions simply makes no sense, legally or otherwise, under the regulatory provisions identified in the allegations, and the regulatory provisions aptly illustrate the lack of legal materiality for False Claims Act liability.

B. Complaint Allegations.

In late 2002 and early 2003, the Relator alleges that he was an independent consultant to Bayer to provide event narratives in the Cipro clinical study. Compl. ¶ 16. Relator alleges no contractual relationship with Quintiles. Relator alleges that the clinical data was falsified by unknown Bayer employees (Joe Doe) and that unknown Quintiles' employees were aware of the data falsification (*i.e.*, John and Jane Doe). Compl. ¶ 25-30. Subsequent to completion of the Cipro study, the FDA approved a six-month period of exclusivity for Cipro in December, 2003. Compl. ¶ 51. Relator appears to allege that during this six-month period of time, December, 2003 to June 2004, any claims submitted to federal health care programs by unknown parties for reimbursement, or paid under unknown federal contracts, constituted a false claim and/or a false statement to obtain payment of a false claim. Compl. ¶ 85, 90, 93, 100-101.

There is no allegation in this action, nor could there be, that Quintiles made any representations to the FDA, filed any reports, submitted any claims for reimbursement, received any federal revenue, negotiated or is a party to any federal health care program contract. In fact, some of these types of actions appear to be asserted only against Bayer in the counts for relief. Compl. ¶ 85, 90, 100, 112, 118, 134. It is alleged with no specifics of any kind that Quintiles conspired with Bayer to present false data to the FDA and obtain reimbursement and contracts from various federal health care programs. Compl. ¶ 104-106. It is not alleged that Quintiles made any false statement or used any false record to get any false claims paid by federal health care programs.

The nature of the alleged false data is not specified but, as generally described, infers potentially phantom clinical study data based on the Relator's alleged medical experience, which is only generally described. Compl. ¶ 56, 59, 64-65. There are no allegations pertaining to any FDA communications with Quintiles or whether Quintiles even prepared or participated in such

communications. Finally, while there are conclusory allegations pertaining to federal health care programs and contracts, there are no specific allegations about the alleged false claims submitted to federal health care programs and exactly what is false about the claim, who submitted the claim and why it is false.

C. Summary of Quintiles' Legal Arguments for Dismissal.

Quintiles denies the fraud allegations in this action and urges this Court to dismiss this action in its entirety on the basis that it is procedurally and substantively defective as a matter of law. Any presumed violation of FDA regulations does not create a cause of action under the False Claims Act. Compliance with the FDA regulatory provisions at issue in this action is not a condition of participation or condition of payment under Medicare or other federal health care program and the alleged violations are not actionable under the False Claims Act under any recognized express certification or implied certification theories, the latter of which has not even been recognized in this jurisdiction. *U.S. ex rel. Kennedy v. Aventis Pharma., Inc.*, No. 03-C-2750, 2008 WL 5211021 (N.D. Ill. Dec. 10, 2008); *see also U.S. ex rel. Thompson v. Columbia/HCA Healthcare*, 125 F.3d 899 (5th Cir. 1997); *U.S. ex rel. Stephens v. Tissue Sci. Labs.*, 664 F. Supp. 2d 1310 (N.D. Ga. 2009). Quintiles contends that violations of regulations unrelated to federal regulatory conditions of payment are not actionable under the False Claims Act. *U.S. ex rel. Gross v. Aids Research Alliance-Chicago*, 415 F.3d 601 (7th Cir. 2005); *U.S. ex rel. Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001). Here, the FDA regulatory provision at issue is wholly unrelated to any condition of payment to any federal health care program and the complaint, on its face, makes no such allegation that reasonably infers any such legal nexus. Counts 1 to 5 of this action should be dismissed on this basis alone.

As to Quintiles, moreover, the allegations fail the heightened pleading standard required under Fed. R. Civ. P. 9(b). Relator's expectation of curing such pleading deficiencies in discovery should be soundly rejected by the Court. The Complaint allegations, though lengthy and conclusory, are inadequate to establish a reasonable inference of actual fraudulent conduct under Fed. R. Civ. P. 9(b) for any of the counts of relief asserted. Moreover, allegations of facially legal conduct that do not specify actual false statements or claims under the False Claims Act do not meet the requirements of Fed. R. Civ. P. 9(b). *Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009) ("it is essential to show a false statement."); *see also U.S. ex rel. West v. Ortho-McNeil Pharma., Inc.*, No. 03-C-8239, 2007 WL 2091185 (N.D. Ill. July 20, 2007); *see also U.S. ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720 (1st Cir. 2007); *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180 (5th Cir. 2009); *Hopper v. Solvay Pharma., Inc.*, 588 F.3d 1318 (11th Cir. 2009); *U.S. ex rel. Polansky v. Pfizer, Inc.*, 2009 WL 1456582 (E.D.N.Y. May 22, 2009); *U.S. ex rel. Radcliffe v. Purdue Pharma L.P.*, 582 F. Supp. 2d 766 (W.D. Va. 2008). Though well pled allegations may be assumed true, there is no required deference to legal conclusions or "threadbare recitals of legal elements which are supported by mere conclusory statements." *See Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949-1950 (2009). The allegations must be sufficiently pled to show more than a mere possibility of actionable wrongdoing. *Id.*

Notably, and further illustrative of the 9(b) deficiencies, this complaint does not even meet the pleading requirements of Fed. R. Civ. P. 10(a) in fully identifying all of the necessary defendant parties and a fishing expedition should not be allowed to find new parties nine (9) years after the alleged misconduct. No federal action should proceed where multiple defense parties are designated as "Doe."

The core statutory structure of the False Claims Act warrants a keen judicial spotlight at the outset of this action because this Court's jurisdiction over a viable *qui tam* action is significantly constrained. As noted by the Court in *U.S. ex rel. Foster v. Bristol-Myers Squibb Co.*, "the focus in an FCA suit must be on the *false claim* itself. As the First Circuit has explained, 'the FCA does not create a cause of action for *all* fraudulent conduct affecting the government.'" 587 F. Supp. 2d 805, 813 (E.D. Tex. 2008) (quoting *U.S. ex rel. Rost v. Pfizer*, 507 F.3d 720, 727 (1st Cir. 2007)) (emphasis in original). "Rather, the fundamental element of an alleged FCA violation is a false or fraudulent claim that is submitted to the government . . . there is no doubt *that the FCA attaches liability not to the underlying fraudulent activity or the government's wrongful payment, but the 'claim for payment.'*" *Id.* (quoting *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999)) (emphasis added and internal quotations omitted). This action presents a novel legal theory asserted with kitchen sink style allegations that do not remotely link to the actual elements of any False Claims Act provision and travels too far beyond the boundaries of the statute and federal pleading standards to be sustained.

D. False Claims Act Retroactivity Issues.

According to the complaint allegations, the alleged misconduct occurred in late 2002 and early 2003. Compl. ¶ 54, 75, 105. The FDA authorization for market exclusivity for unidentified Cipro products occurred in December 2003. Compl. ¶ 51. The sealed complaint was filed in 2009 and Quintiles was aware of the suit by service of the summons in March, 2012. Docket at 1, 36. While this matter was pending under seal, the False Claims Act has been amended twice in the financial industry and health reform legislative efforts that occurred, respectively, in 2009 and 2010. Fraud Enforcement and Recovery Act of 2009, Pub.L No. 111-21, 123 Stat. 1617, 1621 (2009); Patient Protection and Affordable Care Act, Pub. L. No. 111-

148, 124 Stat. 185 (2010). The 2010 False Claims Act amendments are not retroactive and do not appear to relate to this action. *Graham County Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 130 S. Ct. 1396, 1400 n.1 (2010). The 2009 False Claims Act amendments initiated clerical, procedural and substantive changes with provisions for retroactivity that are the subject of varying judicial interpretations. Relevant here, the 2009 amendments to the FCA, effective May 20, 2009, redesignated 31 U.S.C. § 3729(a)(1), § 3729(a)(2), and § 3729(a)(3) as 31 U.S.C. § 3729(a)(1)(A), § 3729(a)(1)(B) and § 3729(a)(1)(C), respectively. The Seventh Circuit has not addressed retroactively definitively or broadly. *See e.g., United States v. Northshore Univ. HealthSystem*, 660 F. Supp. 2d 891, 896 n.4 (N.D. Ill. 2009) (the Court applied the Seventh Circuit's pre-amendment three-element test for Section 3729(a)(1)(B) because of the lack of case law under the post-amendment provision and found that the definition of "material" under the new version of the FCA was reflected in the first element of the pre-amendment test).

The Seventh Circuit has found that Section 3729(a)(1)(B) (formerly Section 3729(a)(2) (false statements) applies to all claims pending on and after June 7, 2008, while Sections 3729(a)(1)(A) (false claims) and (a)(1)(C) (conspiracy) apply to conduct that occurred after May 20, 2009. *See United States ex rel. Yannacopoulos v. Gen. Dynamics*, 652 F.3d 818, 818 n. 2 (7th Cir. 2011). In *United States ex rel. Hudalla v. Walsh Constr. Co.*, No. 05 C 5930, 2011 WL 6028315, at *11-12 (N.D. Ill. Dec. 3, 2011), however, the Court reasoned that in *Yannacopoulos* the Seventh Circuit's statement regarding retroactivity was dicta and did not establish binding precedent on whether Section 3729(a)(1)(B) applies retroactively to a case where, although the lawsuit was pending on and after the effective date of amendments, relators did not allege that any "claims" were pending on or after that date. The Court in *Hudalla* held that the FCA clearly defines "claim" in a matter that does not include legal claims or a lawsuit, but rather a claim for

payment. *Id.* at *11. Thus, the Court found that the pre-amended version of the statute applied to the relator's claims because none of the claims for payment at issue were pending in 2008. *See e.g., Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1327 (11th Cir. 2009); *United States v. Hawley*, No. 06 C 4087, 2011 WL 3295419, at *8-9 (N.D. Iowa Aug. 1, 2011).

Other jurisdictions have addressed retroactivity in different scenarios. *U.S. ex rel. Sanders v. Allison Engine Co., Inc.*, 667 F. Supp. 2d 747, 752 (S.D. Ohio 2009) (retroactivity provision only applies to "claims" pending—not cases—as of June 7, 2008 and noted that a claim is defined as a "request or demand . . . for money or property" under the FCA); *see also U.S. v. Sci. Applications Int'l Corp.*, 653 F. Supp. 2d 87, 107 (D.D.C. 2009) (limiting application of FERA's retroactivity provision to "claims," not cases); *U.S. v. Aquillon*, 628 F. Supp. 2d 542, 550-51 (D. Del. 2009). *But see U.S. ex rel. Carter v. Halliburton Co.*, No. 1:08-cv-1162, 2009 WL 2240331, at *5 n.3 (E.D. Va. 2009) (claims allowed when pending on effective date); *U.S. ex rel. Walner v. Northshore Univ. Healthsystem*, 660 F. Supp. 2d 891, 896 n.3 (N.D. Ill. 2010) (applies three-part test to claims pending at the time of amendment).

Quintiles asserts that the 2009 amendments are not retroactive in this action based upon the fact that both the alleged wrongful conduct and submission of false claims occurred before the May, 2009 amendments, notwithstanding that the action was filed after the May, 2009 amendments. In assessing the nature of the allegations under the applicable standards of Fed. R. Civ. P. 12(b)(6) and 9(b), however, the legal result is the same: the allegations fail to sustain actionable conduct under the pre or post 2009 False Claims Act provisions.

III. Legal Argument.

A. The Allegations Present No Actionable Conduct Under the False Claims Act As A Matter of Law. Regulatory Violations Unrelated, or Material, to Conditions of Payments Are Not Actionable.

The complaint asserts five counts for relief based on violations under distinct three sections of the False Claims Act. Count 1 asserts liability for the knowing presentation of false claims for payment related to the government's purchase of Cipro under Section 3729(a)(1) and appears to limit liability to the time of market exclusivity for Cipro granted by the FDA in December, 2003. Compl. ¶ 84-91. Count 2 asserts liability for making or causing to be made a false statement or record to obtain payment of false claims in the form of unspecified government contracts and payments under Section 3729(a)(2) and appears to limit liability to the time of market exclusivity for Cipro granted by the FDA in December, 2003. Compl. ¶ 92-102. Count 3 asserts liability for conspiracy to cause the payment of false claims and appears to limit liability to the time of market exclusivity for Cipro granted by the FDA in December, 2003. Compl. ¶ 103-110. Count 4 asserts false claims liability for the time period following the expiration of the Cipro market exclusivity under Section 3729(a)(1) (Compl. ¶ 111-123) and, Count 5 asserts false statement or false records liability for the time period following the expiration of the Cipro market exclusivity under Section 3729(a)(2). Compl. ¶ 124 -136. Factual allegations as to Quintiles' alleged conduct or knowledge are noticeably missing.

1. Actionable False Claims Are Not Alleged.

Section 3729(a)(1)(A) of the FCA states in relevant part:

Any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; . . . is liable to the United States Government for a civil penalty...

The Seventh Circuit requires a relator to prove three elements to establish a claim under Section 3129(a)(1): “(1) a false or fraudulent claim; 2) which was presented or caused to be presented, by the Defendants to the United States for payment or approval; and 3) with the knowledge that the claim was false. *United States ex rel. Fowler v. Caremark RX, L.L.C.*, 496 F.3d 730, 740-741 (7th Cir. 2007), *overruled on other grounds by Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907 (7th Cir. 2009). Knowledge is defined generally in the statute as applying to persons that act 1) with actual knowledge of the relevant information; 2) in deliberate ignorance of the truth or falsity of the information; or, 3) in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b); *see e.g., Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672-73 (2008) (FCA requires proof that person knew as “natural, ordinary and reasonable consequence of their actions that false claims would be submitted to the government for payment.”).

There can be no liability under Section 3729(a)(1) unless there is some “claim” presented for payment either directly to the government or to a government grantee or contractor that is paid with funds already received from the government to advance a government interest. *See e.g., United States ex rel. Hudalla v. Walsh Constr. Co.*, No.05-C-5930, 2011 WL 6028315, at *8 (N.D. Ill. Dec. 3, 2011) (finding that, under Section 3729(a)(1), Relator “must show that [defendant] presented a ‘false or fraudulent claim for payment or approval.’”). The FCA, as amended in 2009, defines “claim” as any request for money or property that is presented to an officer, employee, or agent of the United States or made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government’s behalf or to advance a Government program or interest, and if the Government provides or has provided any portion of the money or property requested or demanded or will reimburse such contractor,

grantee, or other recipient for any portion of the money or property which is requested. *See* 21 U.S.C. § 3729(b)(2) *et seq.* Thus, whether a claim is presented to the government itself or a grantee or contractor of the government, some false claim for payment must be presented in order to trigger liability under Section 3729(a)(1)(A).

Some courts have suggested a narrow area of potential liability under Section 3729(a)(1)(A) where, even if the claim presented is not factually false, the underlying contract or government grant by which the claim is submitted was fraudulently induced to extract money from the government that it would not have paid. *See e.g., Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, (4th Cir. 1999); *United States ex rel. Wildhirt v. AARS Forever, Inc.*, No. 09-C-1215, 2011 WL 5373985, at *1-2 (N.D. Ill. Nov. 4, 2011) (the fraud-in-the-inducement theory of liability under Section 3729(a)(1)(A)).” However, even under this theory of liability, as a threshold matter, Relator must be able to prove that there is *some* “claim,” as defined by U.S.C. § 3729(b)(2) *et seq.*, that was presented. *See Harrison*, 176 F.3d at 785 (finding that “the False Claims Act at least requires the presence of a claim—a call upon the government fisc—for liability to attach.”).

Here, as to Quintiles, Relator has not named a single claim or representative example of a claim that Quintiles submitted to the government or to any government contractor or recipient of government funds. Relator also does not allege that Quintiles played any role in actually submitting any claim or had any awareness, knowledge, or participation in any claim that Bayer submitted for reimbursement from the government for the sale Cipro.

2. Actionable False Statements or False Records Are Not Alleged.

Relator also asserts False Claims Act (“FCA”) liability under 31 U.S.C. § 3729(a)(1) against all Defendant parties. Section 3729(a)(1)(B) states in relevant part:

Any person who knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; ... is liable to the United States Government for a civil penalty . . .

The Seventh Circuit imposes liability under this provision if the relator proves three elements: (1) the defendants made a statement in order to receive money from the government; 2) the statement was false, and 3) the Defendants knew it was false. *See Fowler*, 496 F.3d at 741, *overruled on other grounds by Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907 (7th Cir. 2009). As a result of the 2009 amendments to the FCA, this provision requires a showing that the defendant's false record or statement was material to the false claim. This means that the defendant's false statement or record must have "a natural tendency to influence, or be capable of influencing" the government's decision to pay the false claim. 31 U.S.C. § 3729(b)(4). Under this section, liability attaches only when a false statement is used to "coax a payment of money from the government." *Gross v. AIDS Research Alliance-Chicago*, 415 F.3d 601, 604 (7th Cir. 2005). An FCA suit brought under Section 3729(a)(1)(B) and premised upon an alleged false certification of compliance with statutory or regulatory requirements also requires that the certification be a condition of or prerequisite to government payment. *United States ex rel. Crews v. NCS Healthcare of Illinois, Inc.*, 460 F.3d 853, 858 (7th Cir. 2006); *Gross*, 415 F.3d at 604 (citations omitted); *United States v. Omnicare, Inc.*, No. 07-C-5777, 2011 WL 1059148, at *3 (N.D. Ill. March 21, 2011). Where there is an apparent nexus, there may be liability for express false certifications or false statements and records. *In U.S. ex rel. Main v. Oakland City Univ.*, 426 F.3d 914 (7th Cir. 2005), the Seventh Circuit narrowly identified potential False Claims Act liability in an inducement context, where the university allegedly falsely certified its compliance with an agency regulation for which federal subsidy eligibility was conditional. The Court suggested there was potential liability where there is a false statement integral to a causal

chain leading to payment from the federal agency. *Id.* at 916. Here, Bayer's actions in connection with the FDA regulatory provisions for market exclusivity are not causally related to any other agency's determination of benefit or contract for the sale of drug products. The allegations do not present inducement conduct related to the submission of a false claims for payment or reliance on any false statement to make payment on the false claim. The fraud on the FDA theory posits no actionable False Claims Act violation under an express or implied false certification theory.

Relator's reliance on *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, (4th Cir. 1999), to support the legal sufficiency of its fraud-in-the-inducement theory of liability under the False Claims Act is misguided. In *Harrison*, a relator brought an action against a government contractor under the False Claims Act, alleging that the contractor made false statements and false certifications to the government about its need for a sub-contractor and the cost of the sub-contractor in order to induce the government to approve the use of the sub-contractor. *Id.* at 780-81. The Relator argued that because the government's approval was obtained by false statements and a false certification, all the contractor's claims to the government for reimbursement for the sub-contractors' compensation were "false claims." *Id.* at 790-91. The district court dismissed the case for failure to state a claim reasoning that the false statements and certifications "were not made in connection with the presentation of a claim." *Id.* at 780. The Fourth Circuit reversed the district court holding that False Claims Act liability attaches for each claim submitted to the government under a contract, if the contract or extension of government benefit was obtained through false statements or fraudulent conduct. *Id.* at 793-94. See e.g. *United States ex rel. Schwedt v. Planning Research Corp.*, 59 F.3d 196, 199 (D.C. Cir. 1995); *United States ex rel., Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1420

(9th Cir. 1991); *United States ex rel. Wildhirt v. AARS Forever, Inc.*, No. 09-C-1215, 2011 WL 5373985, at *1-2 (N.D. Ill. Nov. 4, 2011).

Unlike in *Harrison*, where the Relator alleged that the defendant made false certifications and statements that led the government to approve the sub-contractor so the defendant could seek government reimbursements for the sub-contractor's expenses, in the present case, Relator has not alleged that Quintiles received any contract, approval or benefit from the government. In fact, the only benefit the Complaint alleges that Quintiles sought in allowing Bayer to submit falsified data was to "not jeopardize...[its] current and future contracts with Bayer." Compl. ¶ 62. The Complaint only alleges one **government** benefit or approval that was fraudulently induced—the government's approval of Bayer's market exclusivity extension. Compl. ¶ 51, 60. Without identifying exactly what benefit, contract, or approval Quintiles fraudulently induced **from the government**, there is no basis for alleging under a fraud inducement theory that Quintiles submitted a false claim. Thus, the Complaint fails on its face to state a claim by which relief can be granted under a fraud-in-the-inducement theory, as to Quintiles, even if every other allegation in the Complaint is true.

Under Section 3729(a)(1)(B), the Relator must also show that the defendant's false record or statement was material to the government's decision to pay the false claim. Here, the regulatory provision that was allegedly undermined by fraudulent conduct is not material to Bayer's product being lawfully in the marketplace and available for sale and use. Relator identifies no contract or reimbursement policy that would preclude the sale or use of Cipro for federal health care programs. Of course, no claims are identified that are legally or factually false, but to the extent this action is premised on the submission of claims on an alleged false certification of compliance with statutory or regulatory requirements, there must also be a

corresponding requirement that the certification be a condition of or prerequisite to government payment. *United States ex rel. Crews v. NCS Healthcare of Illinois, Inc.*, 460 F.3d 853, 858 (7th Cir. 2006); *Gross*, 415 F.3d at 604 (citations omitted); *United States v. Omnicare, Inc.*, No. 07-C-5777, 2011 WL 1059148, at *3 (N.D. Ill. Mar. 21, 2011). This essential element does not exist for alleged non-compliance with the FDA's regulatory provisions pertaining to pediatric exclusivity, which authorizes exclusivity in the agency's discretion for undertaking the study. Whether the study was positive or negative, or performed well, negligently or fraudulently, such regulatory compliance or noncompliance is simply immaterial to payment under any federal health care program or contract.

3. Actionable Conspiracy Is Not Alleged.

Relator asserts False Claims Act ("FCA") liability under 31 U.S.C. § 3729(a)(1)(C) which provides that, "any person who conspires to commit a violation of" Section 3729(a)(1)(A) or Section 3729(a)(1)(B), which are alleged in this Complaint, is liable to the U.S. government. Under Section 3729(a)(1)(C), the general civil conspiracy elements apply. *See e.g., United States ex rel. Durholz v. FKW Inc.*, 189 F.3d 542, 545 n. 3 (7th Cir. 1999) (holding that "general civil conspiracy principles apply" to FCA conspiracy claims); *see also Gross v. AIDS Research Alliance-Chicago*, No. 01 C 8182, 2004 WL 905952, at *9 (N.D. Ill. Apr. 27, 2004). The principal element of civil conspiracy "is an agreement between the parties to inflict a wrong against or injury upon another, and an overt act that results in damage." *Scherer v. Balkema*, 40 F.2d 437, 441 (7th Cir. 1988). Therefore, to prove conspiracy liability under the FCA, Relator must allege sufficient facts to show an agreement between the conspirators to submit a false claim or a false statement or record that was material to a false claim and allege an overt act in furtherance of that agreement, which results in damage. There are no allegations in the

complaint that reference facts for any element of conspiracy; the conspiracy allegations are woefully insufficient to support any plausible inference of actionable conduct.

B. The Complaint Allegations Do Not Meet the Heighted Pleading Standards of Fed. R. Civ. P. 9(b) Compelling Dismissal of this Action.

The allegations in this action show no adherence to the pleading standards of Rule 9(b), which require a plaintiff to specify, at a minimum, the “who, what, when, where, and how” of the alleged fraud, which would constitute “the first paragraph of any news story.” *United States ex rel. Garst v. Lockheed-Martin Corp.*, 328 F.3d 374, 376 (7th Cir. 2003) (quoting *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990); *United States ex rel. Coots v. Reid Hosp. & Health Care Servs., Inc.*, No. 1:10-cv-0526-JMS-TAB, 2012 WL 1098930, at *1 (S.D. Ind. April 2, 2012). Generally, this means, “facts such as the identity of the person making the misrepresentation, the time, place, and content of the misrepresentation, and the method by which the misrepresentation was communicated to the plaintiff [must] be alleged in detail.” *Hefferman v. Bass*, 467 F.3d 596, 601 (7th Cir. 2006). Here, the Relator’s complaint fails to allege to the required degree of particularity the false claims and certifications submitted by Quintiles for the purpose of obtaining payment or approval from the government under Section 3729(a)(1)(A) or the material false statements under Section 3729(a)(1)(B) made by Quintiles, with knowledge of their falsity.

In *Abner v. Jewish Hosp. Health Care Servs.*, No. 4:05-cv-0106-DFH-WGH, 2008 WL 3853361, at *5 (S.D. Ind. Aug. 13, 2008), this court held that although Fed. R. Civ. P. 9(b) does not require proof at the complaint stage, specific allegations are necessary. For three of the five alleged fraudulent billing practices in the *Abner* complaint, the relator named several specific examples as to the fraudulent schemes, including specific patients for whom false claims were submitted, specific dates of the claims, and the name of at least one of the defendant’s employees

who engaged in the fraud. *Id.* at 5-6. *See Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009) (court found allegations were pled with sufficient particularity under Fed. R. Civ. P. 9(b) because relator's complaint named specific details of payment, specific parts shipped on specific dates that were knowingly out of compliance with defendant's government contract, and a specific form that the defendant had to submit with each request for payment, which contained the false statement).

In contrast to *Abner* and *Lusby*, in this action there are several essential allegations patently missing against Quintiles, which include: 1) The identity of Quintiles employees that allegedly falsified data or failed to report false data; the nature of their knowledge, and the time, place and nature of their involvement; 2) any identification of the federal contracts that were improperly awarded to Bayer for the sale of Cipro and any facts alleging Quintiles knowledge of these contracts; 3) any identification of false claims submitted for reimbursement of Cipro or who submitted the false claims or any facts alleging Quintiles knowledge of the falsity of such claims; 4) the identification of the Cipro products at issue in the alleged false study data. These pleading deficiencies are fatal to the viability of this action against Quintiles.

Conclusion

As False Claims Act *qui tam* actions increasingly sail farther away from the legal moorings of the statute, asserting liability for any type of regulatory violation that can be imagined or cobbled together, there are legitimate and substantial threshold questions of whether such allegations present any plausible cause of action. Based on a review of the complaint allegations in this action, and applying established judicial precedent, Quintiles urges this Court to dismiss this action without further leave to amend. The legal theory fails as a matter of law and no facts are pled that establish a viable cause of action. It is highly remote, moreover, and unreasonable to assert, that the Relator can provide additional relevant facts that were not

previously available since the filing of this action three (3) years ago and since the alleged conduct over nine (9) years ago that would cure the substantive legal deficiencies of this action. *Indiana Funeral Dirs. Ins. Trust v. Trustmark Ins. Corp.*, 347 F.3d 652, 655 (7th Cir. 2009) (holding that leave to amend was properly denied because further amendment would have been futile); *Rodriguez v. United States*, 286 F.3d 972, 980 (7th Cir. 2002) (finding that courts may deny amendment of a complaint for undue delay, bad faith, dilatory motive, prejudice, or futility). Accordingly, this action can and should be dismissed with prejudice.

Dated: June 20, 2012

/s/ Kathleen McDermott

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CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the above and foregoing has been served on all counsel of record via the Court's CM/ECF system on the 20th day of June, 2012.

/s/ Kathleen McDermott
